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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,934	10/22/2001	Maria Palasis	12013/60402	8212
23838	7590	01/15/2004		
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			EXAMINER THANH, LOAN H	
			ART UNIT	PAPER NUMBER
			3763	
			DATE MAILED: 01/15/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/982,934

Applicant(s)

PALASIS ET AL.

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 28-45 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 38-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28, 29 and 31-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: \_\_\_\_\_

Art Unit: 3763

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, species I (claims 28-29,31-37,40,41,43 and 44) in Paper No. 5 is acknowledged. The traversal is on the ground(s) that group I and II are sufficiently related and examination of both inventions does not create a serious burden on the Examiner. This is not found persuasive because Applicant is reminded that an application is for one invention. The search for the method claims are not required for the apparatus claims. Applicant has failed to address the actual restriction indicating that the method could be used to used in a different process of using that product such withdrawing /aspirating for diagnostic purposes or other industrial purposes. A serious burden does exist on the Examiner since the search required for the device is not coextensive with the method of using the device and a determination of patentability must be made once for the device and once for the method. Further, the number of the claims is not the issue in restriction requirements.

The requirement is still deemed proper and is therefore made FINAL.

Claims 30,38-45 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group or species, there being no allowable generic or linking claim.

The Examiner agrees with applicant that claims 28 and 33 are generic.

An action on the merits now follows.

***Information Disclosure Statement***

The information disclosure statement filed 10/22/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The Examiner as a courtesy has considered the U.S. Patents which were properly listed in the PTO 1449 and those which were improperly listed in a PTO 892.

***Specification***

The lengthy specification has been checked, however it has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-29,31-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Faxom et al. ( U.S. Patent No. 5,464,395).

Art Unit: 3763

Faxom et al. disclose a catheter system comprising a catheter 5 comprising a shaft having a primary penetrating member 50 and a first penetrating direction and at least one secondary penetrating member 20 wherein each of the at least one secondary penetrating member 20 is retractable and penetrates the tissue in a second different direction that is different from the primary penetrating member. Faxom et al. disclose the second direction to be at an angle that is between 30-90 degrees to the first direction. See col. 5, lines 57-60. See figures 1,8-19.

Claims 28-29,31-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofling ( U.S. Patent No. 5,419,777).

Hofling discloses a catheter system having a catheter comprising a shaft having a primary penetrating member 11 and a first penetrating direction and at least one secondary penetrating member 15 wherein each of the at least one secondary penetrating member 15 is retractable and penetrates the tissue in a second different direction that is different from the primary penetrating member. Hofling discloses the second direction to be lateral to the axial direction as shown in figures 1-3,7. The Examiner is taking the position that the angle is generally perpendicular and between 5-90 degrees.

Claims 28-29 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson ( U.S. Patent No. 4,578,061).

Lemelson discloses a catheter system having a catheter comprising a shaft having a primary penetrating member and a first penetrating direction and at least one secondary penetrating member 57 or 94 wherein each of the at least one secondary

Art Unit: 3763

penetrating member 57 or 94 is retractable and penetrates the tissue in a second different direction that is different from the primary penetrating member. Lemelson discloses the second direction to be lateral to the axial direction as shown in figures 3 and 6. The Examiner is taking the position that the angle is generally perpendicular and between 5-90 degrees.

Claims 28-29,30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough et al. (U.S. Patent No. 5,728,143).

Gough et al. disclose a first 14 and at least one second 16 penetrating member having different penetrating directions. See figures 1-8.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 28-29,31-32 and 33 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 and 15 of prior U.S. Patent No. 6,319,230. This is a double patenting rejection.


**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Abele et al. ( 5,403,311) – see figures 3a to 10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is 703-305-0038. The examiner can normally be reached on Mon-Fri (alternate Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

LT